IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF NORTH CAROLINA
WESTERN DIVISION

SEPRACOR, INC., et al., Plaintiffs, v. BARR PHARMACEUTICALS, INC., et al. Defendants.	)	Western Division No. 5:08-CV-362-H(3)
SEPRACOR, INC., et al., Plaintiffs, v. SANDOZ, INC., Defendant.	)	Eastern Division No. 4:08-CV-89-H(3)
SEPRACOR, INC., et al., Plaintiffs, v. SUN PHARMACEUTICAL INDUSTRIES, LTD., Defendants.	)	Western Division No. 5:08-CV-247-H(3)
SEPRACOR, INC., et al., Plaintiffs, v. SYNTHON PHARMACEUTICALS, INC., et al., Defendants.	)	Western Division No. 5:08-CV-179-H(3)

MEMORANDUM AND RECOMMENDATION

Plaintiffs Sepracor, Inc., UCB S.A., and UCB, Inc. ("Sepracor") allege infringement of United States Patent No. 5,698,558 ("the '558 patent") by Defendants Synthon Pharmaceuticals, Inc., Synthon B.V., Synthon Holding B.V., Synthon Laboratories Inc., and Sandoz, Inc. ("Synthon"). The '558 patent entitled "Methods for Treating Allergic Disorders Using Optically Pure (-) Cetirizine " covers a method of treating allergies using levocetirizine (also known as "(-) cetirizine"), which is the active ingredient in Xyzal, a medication produced by Sepracor. Synthon asserts as affirmative defenses that the '558 patent and its claims are invalid, not infringed, and unenforceable. The parties have asked the Court to construe two elements of claim 2: the term "sedation" and the phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation." For the reasons stated herein, the undersigned recommends that the term "sedation" be construed as: central nervous system impairment, and that the phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation" be construed as: an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, that is sufficient to provide relief from the symptoms of allergic rhinitis but in an amount that does not cause the same degree of sedation caused by a therapeutically equivalent amount of racemic cetirizine.

I. Background

On September 24, 1992, the inventor, Nancy Gray, filed two patent applications. One of these applications led to the issuance of the '558 patent. The other patent application, filed the same date, contained a nearly identical specification and claims. The sole difference between the two applications was that one application claimed the use of (-) cetirizine (levocetirizine), while the other application made the same claims for the use of (+) cetirizine (dextrocetirizine). *See*

[DE-182, Ex. C at 27-35 (original claims in U.S. Patent 5,627,183 prosecution history); DE-182, Ex. D at, *e.g.*, 65 (double patenting rejection)]. As Dr. Gray explained, she filed both applications because she did not know at the time of filing which of the two enantiomers of cetirizine had the anti-allergic activity. [DE-178, Ex. B at 31-33; 55-56]. She also had no knowledge as to which adverse effects of racemic cetirizine, if any, might be avoided by administering only a single enantiomer. [DE-178, Ex. B at 56-57, 77].

Sepracor asserts that Synthon infringed claims 1, 2, 7 and 9. Claims 1 and 2 are independent claims, while claims 7 and 9 depend on claim 2. The parties do not dispute the construction of claims 1, 7 and 9. The parties have asked the Court to construe two elements of claim 2: the term "sedation" and the phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation." In response to this request, the Court held a claim construction hearing on May 24, 2010. [DE-207, 209]. Construction of the claims is therefore ripe for adjudication.

II. Analysis

A claim construction hearing is also known as a Markman hearing, after the Supreme Court's ruling in Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996). In that case, the Supreme Court affirmed a Federal Circuit Court ruling that patent claim construction is a matter to be decided solely by the trial judge and not by a jury. *Id.* at 372. Thus, after Markman, a trial judge construes the meaning of disputed claims within a patent.

In construing a patent claim, a court must first look to the words of the claims themselves. *See* Phillips v. AWH Corp., 415 F.3d 1303, 1312 (Fed. Cir. 2005) (stating that, "[i]t is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which

the patentee is entitled the right to exclude'" (quoting Innova/Pure Water, Inc. v. Safari Water Filtration Systems, Inc., 381 F.3d 1111, 1115 (Fed. Cir. 2004))); s*ee also* Vitronics Corp. v. Conceptronic, Inc., 90 F.3d 1576, 1582 (Fed. Cir. 1996) ("[W]e look to the words of the claims themselves . . . to define the scope of the patented invention.").

Unless otherwise defined by the patentee, the words of the claim must be given "'their ordinary and customary meaning.'" Phillips, 415 F.3d at 1312 (quoting Vitronics, 90 F.3d at 1582). That ordinary and customary meaning is the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention, i.e., as of the effective filing date of the patent application." *Id.* at 1313. This person of ordinary skill in the art "is deemed to read the claim term not only in the context of the particular claim in which the disputed term appears, but in the context of the entire patent, including the specification." *Id.* at 1313. Additionally, this definition by the person of ordinary skill in the art should be that which such a person could ascertain from the "'intrinsic evidence in the record.'" *Id.* at 1314 (quoting Unitherm Food Sys., Inc. v. Swift-Eckrich, Inc., 375 F.3d 1341, 1351 (Fed. Cir. 2004)). Intrinsic evidence in the record includes the words of the patent claim, the specification, and the prosecution history. *Id.* at 1313-14. Thus, "[t]o ascertain the meaning of claims, we consider three sources: the claims, the specification, and the prosecution history." Unique Concepts, Inc. v. Brown, 939 F.2d 1558, 1561 (Fed. Cir. 1991).

Of particular importance is the specification. "[C]laims 'must be read in view of the specification, of which they are a part.'" Phillips, 415 F.3d at 1315 (quoting Markman v. Westview Instruments, Inc., 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc), *aff'd*, 517 U.S. 370 (1996)). The specification may reveal that the inventor gave a patent term a particular definition

that differs from the meaning it would otherwise possess. *Id.* at 1316. Additionally, the specification may make it clear that the inventor disclaimed or disavowed a particular claim scope. *Id.*

> "Ultimately, the interpretation to be given a term can only be determined and confirmed with a full understanding of what the inventors actually invented and intended to envelop with the claim. The construction that stays true to the claim language and most naturally aligns with the patent's description of the invention will be, in the end, the correct construction."

Id. (quoting Renishaw PLC v. Marposs Societa' per Azioni, 158 F.3d 1243, 1250 (Fed. Cir. 1998) (citations omitted)). "'[T]here is sometimes a fine line between reading a claim in light of the specification, and reading a limitation into the claim from the specification.'" Liebel-Flarsheim Co. v. Medrad, Inc., 358 F.3d 898, 904 (Fed. Cir. 2004) (quoting Comark Commc'ns, Inc. v. Harris Corp., 156 F.3d 1182, 1186-87 (Fed. Cir. 1998)).

In considering the specification, a court should evaluate the prosecution history. The prosecution history consists of the exchanges with the United States Patent and Trademark Office (PTO). It "constitutes a public record of the patentee's representations concerning the scope and meaning of the claims, and competitors are entitled to rely on those representations when ascertaining the degree of lawful conduct, such as designing around the claimed invention." Hockerson-Halberstadt, Inc. v. Avia Group Int'l, Inc., 222 F.3d 951, 957 (Fed. Cir. 2000). The entire prosecution history, which includes amendments to claims and all arguments to overcome and distinguish references must be examined. Rheox, Inc. v. Entact, Inc., 276 F.3d 1319, 1326 (Fed. Cir. 2002); Elkay Mfg. Co. v. Ebco Mfg. Co., 192 F.3d 973, 979 (Fed. Cir. 1999). Where an applicant argues that a claim possesses a feature that the prior art does not possess in order to overcome a prior art rejection, the argument may serve to narrow the scope of

otherwise broad claim language. Rheox, Inc., 276 F.3d at 1325 ("Explicit arguments made during prosecution to overcome prior art can lead to narrow claim interpretations . . . . "); Ekchian v. Home Depot, Inc., 104 F.3d 1299, 1304 (Fed. Cir. 1997) ("[S]ince, by distinguishing the claimed invention over the prior art, an applicant is indicating what the claims do not cover, he is by implication surrendering such protection."). A disclaimer must be clear and unambiguous. Omega Eng'g, Inc. v. Raytek Corp., 334 F.3d 1314, 1323-25 (Fed. Cir. 2003).

However, in order to disavow claim scope, a patent applicant must clearly and unambiguously express surrender of subject matter during prosecution. Middleton, Inc. v. Minn. Mining & Mfg. Co., 311 F.3d 1384, 1388 (Fed. Cir. 2002). Thus, in construing the claim, the court considers the prosecution history to determine whether the "patentee disclaimed or disavowed subject matter, narrowing the scope of the claim terms." ACTV, Inc. v. Walt Disney Co., 346 F.3d 1082, 1091 (Fed. Cir. 2003).

A court may also consider extrinsic evidence to determine the meaning of a disputed claim term. Extrinsic evidence is all evidence external to the patent and prosecution history, such as expert and inventor testimony, dictionaries, and learned treatises. Extrinsic evidence, by its very nature, is less reliable than intrinsic evidence in determining how to read a particular patent claim. Phillips, 415 F.3d at 1318. A court must discount expert testimony "'that is clearly at odds with the claim construction mandated by the claims themselves, the written description, and the prosecution history, in other words, with the written record of the patent.'" *Id.* (quoting Key Pharms. v. Hercon Lab. Corp., 161 F.3d 709, 716 (Fed. Cir. 1998)). As such, while extrinsic evidence can be particularly helpful to a court in determining what a person of ordinary

skill in the art would understand claim terms to mean, it must still be considered in the context of the intrinsic evidence. *Id.* at 1319.

During claim construction, "[t]he sequence of steps used by the judge in consulting various sources is not important; what matters is for the court to attach the appropriate weight to be assigned to those sources in light of the statutes and policies that inform patent law." Phillips, 415 F.3d at 1324. The Court will apply these general principles to the evidence and the arguments made by the parties.

III. Construction of Claim 2

The term "sedation" and the phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation"[1] appear in claim 2. Claim 2 reads as follows:

> A method of treating the symptoms of seasonal and perennial allergic rhinitis in a human, while avoiding the concomitant liability of **sedation** associated with racemic cetirizine, which comprises administering to a human in need of such symptomatic relief therapy an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, substantially free of its (+) stereoisomer, **said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation.**

U.S. Patent No. 5,698,558 col. 9, ll. 60-63, col. 10 ll. 1-6 (emphasis added).

A. "But Insufficient to Cause Said Sedation"

The phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation" requires little interpretation. *See* Brown v. 3M, 265 F.3d 1349, 1352 (Fed Cir. 2001) (stating that the claims did "not require elaborate interpretation"). Its ordinary meaning, as understood by a person of skill in the art, is "readily apparent even to lay

[1] While the parties designated the entire phrase, [DE-176 at 5], their dispute is over the final six words, "but insufficient to cause said sedation."

judges, and [such] claim construction . . . involves little more than the application of the widely accepted meaning of commonly understood words." Phillips, 415 F.3d at 1314.

When the word "said" appears before a term in a claim, it carries a special meaning in patent law. "Said" signals that there is a preceding use of that same term earlier in the claim and the drafter is referring back to it. The claim should be read as if the term "said" was replaced by the meaning of the prior claim element that the term "said" refers back to. *See* Baldwin Graphic Sys., Inc. v. Siebert, Inc., 512 F.3d 1338, 1342-43 (Fed. Cir. 2008).

The parties agree that the phrase "said sedation" refers back to the phrase "[the] sedation associated with racemic cetirizine" which appears in the preamble. [DE-186 at 22; DE-189 at 14]. They also agree that the phrase "the concomitant liability of sedation associated with racemic cetirizine" which appears in claim 2 should be construed as "the same level of sedation caused by the administration of a therapeutically equivalent amount of racemic certirizine." [DE-176 at 4].

Synthon urges the Court to construe the disputed phrase as "an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, that is sufficient to provide relief from the symptoms of allergic rhinitis but that is insufficient to cause the sedation caused by a therapeutically equivalent amount of racemic cetirizine." [DE-176 at 5]. Sepracor asks that this phrase be construed as "an amount of (-) cetirizine . . . effective to treat allergic rhinitis with diminished sedation compared to a therapeutically equivalent amount of racemic cetirizine." *Id.* In support of its proposed construction, Synthon argues that the claim "requires that the amount of (-) cetirizine . . . be both (1) sufficient to alleviate the symptoms of allergic rhinitis and (2)

insufficient to cause the sedation caused by a[n] . . . equivalent amount of racemic cetirizine." [DE-178 at 13]. Sepracor argues that there must be "diminished sedation." [DE-180 at 29].

These arguments address a distinction without a difference. Although expressed in different terms, the constructions proposed by each party captures the "meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention," Phillips, 415 F.3d at 1313, that the amount of (-) cetirizine which is administered be enough to be efficacious but not enough to cause the same amount of sedation as racemic cetirizine.

This meaning is confirmed by the specification. The Detailed Description of the Invention in the '558 patent describes the present invention as "avoid[ing] the concomitant liability of adverse effects associated with the administration of the racemic compound by providing an amount which is insufficient to cause the adverse effects associated with the racemic mixture of cetirizine." [DE-182, Ex. A, '558 patent, col. 4, ll. 6-10]. Later, the same section provides that "[u]tilizing . . . (-) cetirizine results in enhanced efficacy [and] diminished adverse effects." *Id.* at col. 5, ll. 10-13.

Synthon argues that the prosecution history demonstrates that "the claim was understood to mean administering (-) cetirizine in therapeutic amounts . . . would not cause sedation." [DE-178 at 14]. Their position misreads the prosecution history.

The claims that eventually led to the issuance of the '558 patent were initially rejected by the patent examiner as obvious over various prior art publications. *See* [DE-182, Ex. E at 102]. In rejecting these claims, the patent examiner explained that "[i]n the absence of experimental evidence demonstrating that the administration of the (-) enantiomer of cetirizine does indeed

avoid side effects associated with the administration of racemic cetirizine, the instant invention remains obvious to one with ordinary skill in the art." *Id.* at 103-04.

In response to the examiner's rejection, Sepracor submitted experimental evidence showing that (-) cetirizine "will provide superior antihistaminic efficacy in the respiratory tract (i.e. in treating asthma and rhinitis) **with little or no sedation**." [DE-182, Ex. F at 129 (emphasis added)]. After considering Sepracor's response, the examiner found that "evidence presented . . . overcomes the obviousness rejection" and the "application [was] allowed to issue." [DE-182, Ex. G at 143].

Sepracor argues that the "[d]efendants merely repeat the claim language and assert that '[t]here is no need to add any definition to the claim language "insufficient to cause" beyond the ordinary and plain meaning of the language'"rather than submitting a proposed construction. [DE-180 at 29]. While Synthon argues that the disputed phrase requires (-) cetirizine to cause no sedation, its proposed construction does not track its argument. [DE-176 at 5]. Rather, it generally follows the plain language of the claim. *See* DSW, Inc. v. Shoe Pavilion, Inc., 537 F.3d 1342, 1347 (Fed. Cir. 2008) (stating that, "absent contravening evidence from the specification or prosecution history, plain and unambiguous claim language controls the construction analysis").

For the foregoing reasons, it is recommended that the phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation" is properly construed as: an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, that is sufficient to provide relief from the symptoms of allergic rhinitis but in an amount that

does not cause the same degree of sedation caused by a therapeutically equivalent amount of racemic cetirizine.

B. "Sedation"

The parties also disagree on the meaning of the term "sedation." Sepracor urges the Court to construe sedation as "symptoms of drowsiness (i.e., somnolence) and impairment (i.e., decreased mental abilities)." [DE-176, pg. 5]. Synthon argues that the Court should construe "sedation" as "central nervous system impairment." *Id.* The parties agree that "impairment" is a component of "sedation" but differ on whether somnolence is. *Id.*

In construing a patent claim, a court must first "look to the words of the claims themselves" which "are generally given [the] ordinary and customary meaning," Vitronics, 90 F.3d at 1582, "that the term would have to a person of ordinary skill in the art in question at the time of the invention." Phillips, 415 F.3d at 1313. The parties submitted evidence supporting their proposed constructions of sedation. That evidence is however, at best, mixed and inconclusive; each proposed construction has some merit and is supported by extrinsic evidence. Accordingly, no "ordinary and customary"meaning can be adduced for the word sedation or from its use in claim 2.

Synthon argues that "[t]he specification and prosecution history of the '558 patent demonstrate unequivocally that the scope of Claim 2 of the '558 patent was limited to 'sedation,' and that the term 'sedation' as used in the specification of the '558 patent did not include 'somnolence.'" [DE-189 at 6]. Where, as here, "the language of the claim does not speak with clarity, we turn to the specification to improve our understanding of the meaning." Neomagic Corp. V. Trident Microsystems, Inc., 287 F.3d 1062, 1071 (Fed. Cir. 2002). A court consults the

specification because "[a] fundamental rule of claim construction is that terms . . . are construed with the meaning with which they are presented in the patent document. Thus claims must be construed so as to be consistent with the specification . . . ." Merck & Co., Inc. v. Teva Pharms., USA, Inc., 347 F.3d 1367, 1370 (Fed. Cir. 2003) (citations omitted).

Title 35, Section 112 of the United States Code provides in pertinent part that

> [t]he specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.
>
> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

In order to ascertain the meaning of sedation, the Court will examine both the specification and prosecution history.

Racemic cetirizine is a second generation H_1 histamine receptor antagonist. [DE-182, Ex. A, '558 patent, col. 2, ll. 39-42]. It is used primarily in treating seasonal and perennial allergic rhinitis and generally offers some significant advantages beyond the first generation compounds. *Id.* at col. 2, ll. 13, 14 and 42-44. The specification teaches that although racemic cetirizine has advantages over the first generation antihistamines, "some adverse events remain." *Id.* at col. 3, ll. 36-37. These include "sedation and somnolence" *Id.* at col. 3, ll. 37-45.

The specification also teaches that

> This invention relates to novel compositions of matter containing optically pure (-) cetirizine . . . [which] possess potent activity in treating seasonal and perennial allergic rhinitis . . . . (-) certirizine provides this treatment which avoiding adverse effects, including, but not limited to, sedation and somnolence . . . which are associated with the administration of the racemic mixture of cetirizine.

Id. at col. 1, ll. 11-33. Simply stated, the goal of the invention was to find a compound "with the advantages of the racemic mixture of cetirizine which would not have [its] disadvantages." *Id.* at col. 3, ll. 42-45.

Sepracor claims that

> [t]here is no indication in the specification of the '558 patent that the terms [sedation and somnolence] are used differently. Rather, the specification refers to "sedation" and "sedation and somnolence" interchangeably with no indication of any difference in meaning. (*See*, *e.g.*, Exh. 1, '588 patent, 1:23-25 ("sedation and somnolence"); 2:45 ("less sedation"); 2:54-58 ("sedative side effects"); 3:34-36 ("reduced sedation"); 3:36-39 ("some incidence of sedation and somnolence"); 3:41-42 ("adverse effects, including sedation and somnolence")).

[DE-180 at 22].

However, in each instance except the first, where the terms sedation and somnolence are paired, the benefits described in the specification are the benefits of racemic cetirizine. Rather than confirming Sepracor's position, the references to both "sedation and somnolence" in the specification strongly indicate that the two terms have different meanings. Sepracor does not attempt to explain how the linked use of sedation and somnolence throughout the specification, including in the list of adverse effects, can be read as somnolence being included in the term sedation. Rather, their argument resorts to *ipse dixit*.

The prosecution history of the '558 patent supports Synthon's construction of sedation. The claims that led to the eventual issuance of the '558 patent were initially rejected by the patent examiner as obvious over various prior art publications. *See* [DE-182, Ex. E at 102]. In rejecting these claims, the patent examiner explained that "[i]n the absence of experimental evidence demonstrating that the administration of the (-) enantiomer of cetirizine does indeed

avoid side effects associated with the administration of racemic cetirizine, the instant invention remains obvious to one with ordinary skill in the art." *Id.* at 103-04.

In its response to the examiner's rejection, Sepracor submitted evidence from a number of experiments that "the administration of the (-) enantiomer of cetirizine does indeed avoid side effects associated with the administration of racemic cetirizine" and argued "the *prima facie* case of obviousness is believed overcome." [DE-182, Ex. F at 129]. Earlier in the same response, Sepracor noted "[f]rom these results one may conclude . . . that the (-) enantiomer will provide superior antihistaminic efficacy in the respiratory tract (i.e. in treating asthma and rhinitis) **with little or no sedation**." *Id.* (emphasis added).

When originally filed, Claim 2 read:

> A method of treating the symptoms of seasonal and perennial allergic rhinitis in a human, while avoiding the concomitant liability of **adverse effects** associated with racemic cetirizine, which comprises administering to a human in need of such symptomatic relief therapy an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, substantially free of its (+) stereoisomer, said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said **adverse effects**.

[DE-182, Ex. I at 54 (emphases added)]. The phrase adverse effects is defined in the '558 patent's specification as including "but . . . not limited to, sedation and somnolence, headache, gastrointestinal disturbance, dizziness, nausea, cardiac arrhythmias and other cardiovascular effects." '558 patent, col. 5, ll. 16-20. In its response to the examiner's rejection, Sepracor amended and narrowed claim 2 by replacing the broad term "adverse effects" with the more specific term "sedation." *See* [DE-182, Ex. F at 123-24]. Based on Sepracor's submission the claims of the '558 patent were allowed. *See* [DE-182, Ex. G at 143]. The examiner expressly relied on Sepracor's representation that it had presented evidence that "(-) cetirizine avoids

adverse side effects associated with (+) cetirizine" in allowing the application to issue. *Id.* It is apparent that the amendment of claim 2 to change the claimed benefits from "adverse effects," which included both sedation and somnolence, to "sedation" narrowed the scope of and removed the term somnolence from claim 2.[2] The amendment was made to overcome the examiner's rejection and thus related to patentability. *See* Elekta Instrument S.A. v. O.U.R. Scientific Int'l, Inc., 214 F.3d 1302, 1308 (Fed. Cir. 2000) (citing Graham v. John Deere Co., 383 U.S. 1, 33 (1966) ("Claims that have been narrowed in order to obtain issuance over the prior art cannot later be interpreted to cover that which was previously disclaimed during prosecution."); *see also* Schriber-Schroth Co. v. Cleveland Trust Co., 311 U.S. 211, 220-21 (1940) ("It is a rule of patent construction consistently observed that a claim in a patent as allowed must be read and interpreted with reference to claims that have been cancelled or rejected, and the claims allowed cannot by construction be read to cover what was thus eliminated from the patent."). Therefore, somnolence is no longer among the disadvantages of racemic cetirizine that the invention avoids. A contrary conclusion would allow Sepracor to insist that sedation still embraced not only somnolence but all of the original adverse effects. It is therefore recommended that the term "sedation" be construed as: central nervous system impairment.

The parties rely on extrinsic evidence, their experts' depositions, and reports and articles to support their contentions. But these do little more than illustrate the problem with extrinsic evidence; it is often ambiguous and less reliable than intrinsic evidence.[3] Some examples should suffice to illustrate the problem.

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[2] While the term somnolence never explicitly appeared in claim 2, it was present by virtue of its inclusion in the term adverse effects.

[3] As explained in Phillips:

Sepracor relies on the Casale [DE-182, Ex. R.] and Campoli-Richards [DE-191, Ex. V] articles to support their contention that the term "sedation" includes both a subjective (somnolence) and an objective (impairment) component. [DE-180 at 12]. That reliance is misplaced. The Casale article was published in 2003, some eleven years after the '558 patent was filed. That reason alone lessens its value. More importantly, the article defines sedation with the important qualification "*(s)edation* [as] used in this article." [DE-182, Ex. R. at 3]. Clearly, the authors limited the scope of their definition to the article and did not purport to define the term sedation more generally.

Dr. Gelfand, one of the article's authors, wrote in his expert report that the meaning of sedation had not changed from 1992 to 2003, and that "[t]he term 'sedation' as I generally understand it (and as it is generally understood) is an umbrella term for central nervous system effects, including both impairment and somnolence/drowsiness." [DE-180, Ex. 5 at 7]. While

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> We have viewed extrinsic evidence in general as less reliable than the patent and its prosecution history in determining how to read claim terms, for several reasons. First, extrinsic evidence by definition is not part of the patent and does not have the specification's virtue of being created at the time of patent prosecution for the purpose of explaining the patent's scope and meaning. Second, while claims are construed as they would be understood by a hypothetical person of skill in the art, extrinsic publications may not be written by or for skilled artisans and therefore may not reflect the understanding of a skilled artisan in the field of the patent. Third, extrinsic evidence consisting of expert reports and testimony is generated at the time of and for the purpose of litigation and thus can suffer from bias that is not present in intrinsic evidence. The effect of that bias can be exacerbated if the expert is not one of skill in the relevant art or if the expert's opinion is offered in a form that is not subject to cross-examination. *See* Senmed, Inc. v. Richard-Allan Med. Indus., Inc., 888 F.2d 815, 819 n.8 (Fed. Cir. 1989). Fourth, there is a virtually unbounded universe of potential extrinsic evidence of some marginal relevance that could be brought to bear on any claim construction question. In the course of litigation, each party will naturally choose the pieces of extrinsic evidence most favorable to its cause, leaving the court with the considerable task of filtering the useful extrinsic evidence from the fluff. *See* Daubert v. Merrell Dow Pharms., Inc., 509 U.S. 579, 595 (1993) ("Expert evidence can be both powerful and quite misleading because of the difficulty in evaluating it."). Finally, undue reliance on extrinsic evidence poses the risk that it will be used to change the meaning of claims in derogation of the "indisputable public records consisting of the claims, the specification and the prosecution history," thereby undermining the public notice function of patents. Southwall Techs., 54 F.3d at 1578.
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> Phillips, 415 F.3d at 1318.

both statements support Sepracor's contention that sedation included both impairment and somnolence, Dr. Gelfand noted that "during the prosecution of the patent, the claim terms were changed from 'adverse effect' to 'sedation' thereby eliminating the reference to somnolence." *Id*. From this he concluded that

> [b]y changing the claim to refer to only "sedation" from the list of adverse effects originally included in the specification, the patent applicant has excluded somnolence from the claim. Therefore, a person of ordinary skill in the art would have understood that the term "sedation" as used in the claims of the '558 patent is limited to central nervous system impairment.

Id. at 8. Thus, rather than supporting Sepracor's position, Dr. Gelfand undercuts it.

The Campoli-Richards article analyzed the adverse effects of cetirizine in a number of comparative studies. Sepracor points to a sentence in the article, "literature cited in the '558 patent . . . teaches that '[m]ost researchers appear to include measures of "drowsiness" together with parameters of cognitive impairment, or regard both effects as part of a continuum of CNS effects.'" [DE-186 at 8 (citation omitted)]. However, Sepracor never explains or refers to the Campoli-Richards article's lead sentence in the paragraph: "While CNS effects are well recognized as being associated with classic H_1-receptor antagonist therapy, **there appears to be no general agreement in the published literature on the meaning of 'sedation' as applied to antihistamines**." [DE-183, Ex. 7 at 11 (emphasis added)].

The Campoli-Richards article also refers to "the incidence of sedation **and/or** somnolence." *Id.* at 4 (emphasis added). Taken together the assertion that there is "no general agreement . . . on the meaning of 'sedation' as applied to antihistamines" and the use of "and/or" eviscerates Sepracor's argument that a person of ordinary skill in the relevant art would understand that the term sedation includes both impairment and somnolence.

Sepracor argues that "[d]efendant's expert Professor Ian Hindmarch similarly agreed that the ordinary understanding of 'sedation' includes both somnolence and impairment." [DE-180 at 21]. But the evidence they cite does not support their argument. Dr. Hindmarch wrote: "'Sedation' has **sometimes** been used to refer to both CNS impairment as determined by overt or objective measures and somnolence as determined by subjective measures." [DE-180, Ex. 13 at 5 (emphasis added)]. By qualifying his opinion with the word "sometimes," Dr. Hindmarch further illustrates the problem with extrinsic evidence.

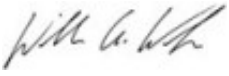
The waters are further muddied by Sepracor's expert Dr. Michael Blaiss. In his Rebuttal Report, Dr. Blaiss presents his "opinion that one of skill in the art would not consider somnolence as separate and distinct from 'central nervous system impairment' and that both describe sedation." [DE-180, Ex. 6, ¶ 7]. However, earlier in that report he states "it is my opinion that the term 'sedation' is understood by clinicians and others in the allergy field to mean an effect on the central nervous system described by patients as **drowsiness, tiredness, somnolence and the like**." *Id.* at ¶ 5 (emphasis added). While this definition seemingly excludes the objective component, later he references his work on the Casale article. There, he opined that "sedation can consist of subjective feelings of drowsiness (sleepiness, lethargy, subtle confusion), objective measures of impairment (slowed reaction time, impaired attention and working memory, and perceptual changes), or both." *Id.* at ¶ 8. Finally, he writes "[a]s a physician who sees patients suffering from allergic rhinitis on a daily basis, a subjective patient evaluation is the most pertinent information a physician considers when contemplating treatment of the disease." *Id.* at ¶ 10. He also points out that clinical trials and observational studies "rely on subjective patient reports to evaluate both efficacy and sedative side effects." *Id.* But what a

"physician considers when contemplating treatment of the disease" or what a study relies on "to evaluate both [the] efficacy and sedative side effects" of drugs has little to do with what the term sedation means. It is clear from these examples that the extrinsic evidence offered in this case demonstrates only that the meaning of the term "sedation" is in the eye of the beholder.

IV. Conclusion

The specification and prosecution history of the '558 patent support Synthon's construction of the term "sedation." As for the phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation," the undersigned discerns no meaningful distinction between the parties' constructions. For the foregoing reasons it is hereby RECOMMENDED that the term "sedation" be construed as: central nervous system impairment, and that the phrase "said amount being sufficient to alleviate or palliate said allergic rhinitis but insufficient to cause said sedation" be construed as: an amount of (-) cetirizine, or a pharmaceutically acceptable salt thereof, that is sufficient to provide relief from the symptoms of allergic rhinitis but in an amount that does not cause the same degree of sedation caused by a therapeutically equivalent amount of racemic cetirizine.

SO RECOMMENDED this the 8th day of September, 2010.



WILLIAM A. WEBB
UNITED STATES MAGISTRATE JUDGE